

**DRUG LITERATURE EVALUATION
PPRA 0473
SPRING QUARTER 2001-2002**

Class Hours:

Lecture

Mondays, 9:10 to 10:00, LTC-C (except 3/18, 4/8, 4/22 & 4/29)

Wednesdays, 11:10 to 12:00, ERC-W

March 18th: **No class**. Use this time as a library day to work on Part I of your DI paper.

April 8th: You will be taking a PPRA 0493 exam during your scheduled class time. This class will meet on

Tuesday, April 9th from 2:10 – 3:00 in ERC-E.

April 22nd: You will be taking a PPRA 0443 exam during your scheduled class time. This class will meet **later this day from 1:10 – 2:00 in ERC-E.**

Workshop

Monday, April 29th, 8:10 – 10:00, MDLs (see assignment for exact times and details)

Instructors:

David P. Zgarrick, Ph.D. (Course Coordinator, Primary Literature Evaluation, Special Topics)

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Course Web Site:

<http://mwunet.midwestern.edu/academic/DLE/index.htm>

Required Course Materials:

Ascione, F.J. Principles of Scientific Literature Evaluation: Critiquing Clinical Drug Trials. American Pharmaceutical Association: Washington, D.C. 2001. (available from Matthews Bookstore and APhA (1-800-878-0729))

A course packet containing all handouts and readings for the course must be purchased from Matthews Bookstore. Handouts and readings will not be distributed in class or on the course web site.

Credit Hours: 2.0

Course Description:

This course introduces students to critical evaluation of the medical literature. Emphasis is placed on critical thinking and problem solving skills necessary to answer drug information questions, evaluate medication-related events, and resolve issues regarding medication use. Individual and group activities will focus on analysis of the literature, application of problem solving skills, and practice of verbal and written communication skills.

Course Objectives:

Upon successful completion of this course, the student will be able to:

1. Critically evaluate clinical trials published in the pharmacy and medical literature.
2. Use the primary literature to respond to practice-related questions.
 - a. Apply the systematic approach to answering a drug information request.
 - b. Write a clear and concise drug information consult.
 - c. Present a research article in a journal club format.
3. Evaluate and apply other types of research studies published in the pharmacy and medical literature
 - a. Intention-to-Treat Analysis
 - b. Pharmacoepidemiology
 - c. Meta Analysis
 - d. Pharmacoeconomics

Course Policies:

Lectures: The purpose of lectures in this course will be to explain concepts related to primary literature evaluation and communicating the findings of a critical evaluation to various audiences (e.g., physicians and other health care professionals, pharmacists, pharmacy students and residents, patients).

Attendance at lectures is not required, but is **highly recommended** in order to fully understand the concepts that are being discussed. Many lectures will involve the evaluation of articles that will be distributed in the course packet. Students are **highly recommended** to read these articles prior to attending class.

Exams: Students will be provided with a clinical trial in their course packet to review for Exams #1 & #2. This trial will be the basis for both exams. Students will be asked a series of 30 – 40 questions on each exam in which they will apply what they have learned in the Primary Literature Evaluation lectures to critically evaluate this clinical trial.

A series of on-line practice quizzes have been developed to help students gain experience in critically evaluating clinical trials and answering questions similar to those posed on the exams. These questions are all based on another article which can be found in the course packet. Links to the on-line quizzes can be found on the course web site.

Attendance at exams is **required**, and students are expected to make every effort to be at exams **on time**. Students who are late for any exam will be allowed to take the exam **only at the discretion of the course coordinator**. Students who arrive for an exam after any student has left the room will not be allowed to take the exam at that time. They may be allowed to take a make-up exam if their absence is deemed excused (see page 3).

All seating for exams will be **assigned**. Please see the doors outside of the exam room for your seating assignment immediately prior to each exam.

Exams will not be returned to students. Students are encouraged to make an appointment with the course coordinator to review their exams. Exams will be retained for a period of one year from the start of the quarter, after which time they will be disposed of in a confidential manner.

Written Drug Information Question and Answer: Each student will identify a drug information question, which is specific to a patient population and requires using two clinical trials in published in primary literature to answer the question. The goal of the assignment is to provide a complete, correct, patient-tailored, and timely response to the original question. Thus, it will be required that:

- a. the systematic approach to answering a drug information question be used.
- b. a search through tertiary, secondary, then primary literature be conducted.
- c. two published clinical trials be analyzed and that that analysis be incorporated into the response, along with other tertiary and secondary literature.
- d. a response be formulated tailored to a specific patient population.

- e. the response be appropriately referenced, using the formats for references described in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (N Engl J Med 1997;336:309-313.).
- f. the question, response and copies of literature used to develop the response will be submitted prior to or by the deadline.

All of the instructions and forms needed to complete this assignment can be found in the course packet. There are two deadlines for the assignment. Step 1 of the assignment (Identifying a Drug Information Question and Conducting the Literature Search) will be due at the beginning of class on March 27th (11:10 AM). Step 2 of the assignment (Completed Drug Information Question and Answer) may be submitted anytime prior to 5:00 PM on Friday, May 3rd.

Journal Club Workshop: A Journal Club workshop will be held on Monday, April 29th. Attendance at this workshop is **required**. Approximately one week prior to the workshop, students will be assigned to a four-student group, a time and room to meet (either 8:10 – 9:00 AM or 9:10 – 10:00 AM), and an article to review from the course packet. Students will individually evaluate and prepare written responses to a series of questions about their article prior to the workshop. Student groups will then perform a Journal Club in workshop in a manner similar to that demonstrated in class on April 22nd. Students will be graded on their individual written work prior to the workshop, their level of preparedness and quality of group interaction in the workshop, and a peer evaluation completed by fellow group members after the workshop.

Extra Credit: The course coordinator may offer up to three **unannounced** quizzes during the quarter. These five-minute quizzes will be held at the beginning or end of a class session, and will consist of five questions (each worth one point). The questions will be based on material covered in the previous class session or material assigned for the current class session.

Given that these quizzes will be for extra credit, only those students who are in attendance at the class session will be able to take the quiz. Make-up quizzes will not be offered, regardless of whether your absence is excused or unexcused.

Exam Procedures

The CCP Faculty has approved the following set of exam procedures. These procedures will apply to all examinations given in any CCP course (including this course).

1. All personal belongings should be placed in an area designated by the instructor/ proctor. Only items required by the instructors/proctors should be in sight on the desk.
2. During the exam:
 - a. Brimmed hats (e.g. baseball hats) should be worn backwards (or not at all);
 - b. No sunglasses or mirrored glasses may be worn;
 - c. Cell phones, pagers and personal digital assistants (e.g., Palm Pilot) must be left with personal belongings and must be set to operate in a "silent" mode.
3. Only college-approved calculators (without covers) may be used for exams.
4. All students must stop writing and immediately place their writing utensils on the desk when the end of the exam period is announced. Faculty are permitted to assess a grading penalty to students who continue to work, as described in the course syllabus. (Note: In this course, the penalty for continuing to work on an exam after time has been called is 10% of the points for the exam).
5. Students must turn in all exam materials before leaving the exam room. Portions of the exam may be returned at a later time depending on the policy of the instructor. (Note: In this course,

exam materials will not be returned. Students may set up an appointment with the course coordinator to view their exams at any time.)

6. The proctors are obligated to provide verbal warning or move a student to another seat if: 1) a student appears to be gazing at another student's work; 2) a student appears to be talking or signaling answers; 3) neglects to protect his/her answer sheet from view of other students; or 4) a student is sitting near a student who is gazing at their work. Such interventions are not of a personal nature. To avoid such interventions, every student is required to keep their eyes on their own work, shield their work from the view of others, and otherwise avoid any appearance of suspicious behavior.

Missing required workshops and exams: When a student knows that they are going to miss a workshop or exam under circumstances where an excused absence may be granted (documented illness, family emergency, others at the discretion of the course coordinator), the course coordinator must be notified **immediately**. The course coordinator can be contacted at his office (515-6965) or through the Department of Pharmacy Practice secretary (515-6115). These telephone numbers are both available **24 hours a day** (please leave a message if there is no answer). You must contact the course coordinator or leave a message **before** you will miss a workshop or exam in order to be granted an excused absence. The course coordinator will be the sole person to determine if an absence from a required class session is excused.

Students who have been granted an **excused absence from a workshop** will not have to make up the assignment; their final grade will be determined based only on the exams and DLE consult. Students who have been granted an **excused absence from Exam #1 or #2** will take an essay make-up exam on Friday, May 17th at 9 AM.

Academic Honesty: Acts of academic and professional misconduct are defined in the 2001-2002 Midwestern University Student Handbook. All acts of academic and professional misconduct are forbidden in this course. All CCP and MWU policies and procedures regarding academic honesty will be followed and enforced. Penalties that may be assessed for any act of academic or professional misconduct include, but are not limited to: a lower grade for the work involved; no credit ("0" grade) for the work involved; a lower grade for the course; suspension from the course; automatic failure of the course; and/or expulsion from the program.

Of particular importance in this course is plagiarism. Plagiarism is using the ideas and words of others without clearly acknowledging the sources of information. Dr. Lee has provided information about plagiarism in the course packet. The course coordinator intends to use electronic means to detect plagiarism. These may include (but are not limited to) comparing the written content of all DI papers against (1) DI papers written by other students in the course, (2) DI papers written by past students in the course, (3) DI papers written by students on rotations, and (4) content found on the Internet.

Grading: 500 total possible points

- 100 pts Exam 1
- 100 pts Exam 2
- 50 pts Journal Club Workshop
 - Pre-workshop individual written assignment = 25 points
 - Facilitator assessment of group performance = 15 points
 - Peer evaluation of individual performance = 10 points
- 250 pts Drug Literature Evaluation Written Consult
 - Step 1 = 35 points
 - Step 2 = 215 points

Course grades will be based on the following scale:

450 (90%) – 500 A

400 (80%) – 449	B
360 (72%) – 399	C
325 (65%) – 359	D
Below 325 (<65%)	F

Class Schedule – Drug Literature Evaluation (PPRA 0473) – Spring 2002

Week	Date	Time	Topic	Instructor
1	3/4/02	9:10-10:00	Course introduction	Zgarrick
	3/6/02	11:10-12:00	DI Review	Lee
2	3/11/02	9:10-10:00	Preparing Written Drug Information Responses	Lee
	3/13/02	11:10-12:00	Guidelines for DI Papers on Rotations	Burkiewicz
3	3/18/02		Library Day – No class	
	3/20/02	11:10-12:00	Primary Literature Evaluation	Zgarrick
4	3/25/02	9:10-10:00	Primary Literature Evaluation	Zgarrick
	3/27/02	11:10-12:00	Primary Literature Evaluation Step 1 of DI Assignment due at beginning of class	Zgarrick
5	4/1/02	9:10-10:00	Primary Literature Evaluation End of Exam #1 Material	Zgarrick
	4/3/02	11:10-12:00	Primary Literature Evaluation	Zgarrick
	4/4/02	8:30 – 10:00	Exam #1 – L101 & L102 McNutt	
6	4/9/02	2:10-3:00	Primary Literature Evaluation	Zgarrick
	4/10/02	11:10-12:00	Primary Literature Evaluation	Zgarrick
7	4/15/02	9:10-10:00	Primary Literature Evaluation End of Exam #2 Material	Zgarrick
	4/17/02	11:10-12:00	Preparing for Journal Club	Burkiewicz
	4/18/02	8:30 – 10:00	Exam #2 – L101 & L102 McNutt	
8	4/22/02	1:10 – 2:00	Sample Journal Club – Clinical Trial	Bruce Burkiewicz Chavanu
	4/24/02	11:10-12:00	Special Topics – Meta Analysis	Zgarrick
9	4/29/02	8:10–10:00	Journal Club Workshop – Rooms TBA See assignment for details	Clinical Faculty
	5/1/02	11:10-12:00	Special Topics – Intention-to-Treat/Pharmacoepidemiology	Zgarrick
	5/3/02	No later than 5 PM	Written Drug Information Response Due All parts must be delivered to the Pharmacy Practice Office (see assignment for details)	
10	5/6/02	9:00-9:50	Special Topics – Pharmacoepidemiology	Zgarrick
	5/8/02	11:10-12:00	Special Topics – Pharmacoeconomic Studies	Zgarrick
Finals Week			<u>No Final Exam Scheduled!</u>	

